

REMARKS

Upon entry of the present amendment, claims 1-8, 10-20, and 22-24 are pending in the application. Claims 9, 21 and 25-77 have been cancelled without prejudice or disclaimer. Claims 1-8 and 13-20 have been amended. The present amendments are fully supported by the specification and the claims as originally filed. For example, support for the amendments to independent claims 1 and 13, as amended herein, is found at least at page 13, lines 19-21; at page 18, lines 18-30; and at page 29, lines 8-23. Accordingly, no new matter has been added by this filing.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 13-24 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite. In particular, the Examiner has indicated that the phrase “A method of growth” is indefinite.

Independent claim 13 has been amended to correct an inadvertent typographical error. As amended, claim 13 is directed to a method of inhibiting growth”. Applicants submit that amended claim 13 and its dependent claims are clear and definite. Accordingly, withdrawal of this rejection is requested.

Rejections under 35 U.S.C. § 103

Pfirrmann and Morrissey

Claims 1, 8-13, 20-26, 30-34, 45-58 and 74-76 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,593,665 by Pfirrmann *et al.* (“Pfirrmann”) in view of International Publication No. WO 98/52572 by Morrissey *et al.* (“Morrissey”). According to the Examiner, “it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the teachings of Pfirrmann on the use of taurolidine and taurultam in treating tumors, by adding the method of treatments as taught by Morrissey, because of the expectations of treating patients in need of such treatments with the most effective medications and the least possible amount of side effects.” (Office Action, page 4).

Independent claim 1 has been amended to recite a method of inhibiting growth of a recurrent autologous tumor in a mammal by administering to the mammal a composition comprising taurolidine or a biologically active derivative thereof, in an amount sufficient to

induce tumor cell death by apoptosis. Claim 13, as amended, is directed to a method of inhibiting growth of a recurrent autologous tumor in a mammal by administering to the mammal a composition comprising taurultam or a biologically active derivative thereof, in an amount sufficient to induce tumor cell death by apoptosis.

Pfirrmann and Morrissey, alone or in combination, do not disclose or suggest the use of taurolidine, taurultam and/or biological derivatives thereof to inhibit the growth of a recurrent tumor. Thus, there is no teaching or suggestion in this reference that would provide the skilled artisan with a reasonable expectation that taurolidine, taurultam and/or biological derivatives thereof would successfully inhibit the growth of a recurrent tumor, such as, for example, a recurrent glioblastoma or a recurrent ovarian tumor. Accordingly, Applicants submit that the amended claims presented herein are not rendered obvious by the Pfirrmann and Morrissey references. Withdrawal of this rejection is, therefore, requested.

Pfirrmann, Morrissey and Samid

Claims 2-7, 14-19, 27-29, 35-44, 49-51 and 74-76 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Pfirrmann in view of Morrissey, and in further view of U.S Patent No. 5,661,179 by Samid (“Samid”). According to the Examiner, “it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the combined teachings of Pfirrmann and Morrissey by substituting phenylacetate of Samid with taurolidine and/or taurultam, with a reasonable expectation of successfully producing compositions and methods of treatment for various tumors.” (Office Action, page 5).

As described above, the pending claims have been amended to recite methods of inhibiting recurrent tumors in a mammal using taurolidine, taurultam and/or biological derivatives thereof.

For all of the reasons set forth above, Pfirrmann and Morrissey, alone or in combination, do not disclose or suggest the use of taurolidine, taurultam and biological derivatives thereof to inhibit the growth of recurrent tumors. The teachings of Samid fail to remedy the deficiencies in the teachings of the Pfirrmann and Morrissey references, as Samid does not teach or suggest the use of any compounds to inhibit the growth of a recurrent tumor, let alone the use of taurolidine, taurultam and/or biological derivatives thereof. Thus, these references, alone or in combination, fail to render the methods recited by the amended claims obvious. As such, Applicants request that the Examiner withdraw this rejection.

Monson

Claims 1-51 and 74-76 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over International Publication No. WO 92/00743 by Monson (“Monson””). According to the Examiner, “it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the Monson’s teachings by branching off methods of treatment, prophylaxis and types of tumors.” (Office Action, page 6).

As described above, the pending claims have been amended to recite methods of inhibiting recurrent tumors in a mammal using taurolidine, taurultam and/or biological derivatives thereof.

In contrast to the methods recited by the amended claims presented herein, Monson fails to describe or suggest any methods of treating recurrent tumors in a mammal using taurolidine, taurultam and/or biological derivatives thereof. Accordingly, Applicant submits that the amended claims presented herein are not rendered obvious by the Monson reference. Withdrawal of this rejection is, therefore, requested.

Double Patenting Rejections

Statutory (35 U.S.C. § 101) Double Patenting Rejections

Claims 52-73 have been rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-22 of prior U.S. Patent No. 6,429,224, while claim 77 has been rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-22 of prior U.S. Patent No. 6,703,413.

Applicants note that claims 52-73 and 77 have been canceled, thereby rendering all rejections of these claims moot. Accordingly, these rejections should be withdrawn.

Non-Statutory Double Patenting Rejections

Claims 1, 8-13, 20-26, 30-34, 45-58 and 74-76 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,703,413 (“the ‘413 patent”). Claims 1-77 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-43 of U.S. Patent No. 6,995,164 (“the ‘164 patent”). Claims 71-72 have been rejected

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under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,812,251 (“the ‘251 patent”). Claims 1-77 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of co-pending U.S. Application No. 10/980,359 (“the ‘359 application”). Claims 1-77 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of co-pending U.S. Application No. 11/350,313 (“the ‘313 application”).

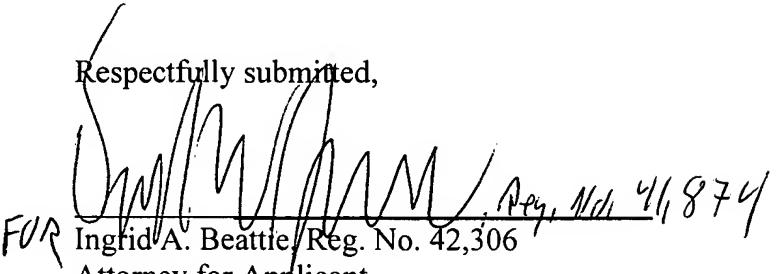
As described above, the pending claims have been amended to recite methods of inhibiting recurrent tumors in a mammal using taurolidine, taurultam and/or biological derivatives thereof.

However, none of the cited patents claim the use of taurolidine, taurultam and/or biological derivatives thereof to inhibit the growth of a recurrent tumor by administering these compounds after therapeutic intervention for a primary tumor as recited by the amended claims. Accordingly, Applicants submit that the methods recited by the amended claims are not obvious in view of the claims of the cited patents and applications. As such, the methods of the claimed invention are patentably distinct from the cited references, and Applicants respectfully request that these rejections and provisional rejections be withdrawn.

CONCLUSION

Applicants submit that the application is in condition for allowance and such action is respectfully requested. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact any of the undersigned at the telephone number provided below. The Commissioner is hereby authorized to charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 21486-031 CON2.

Respectfully submitted,


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